PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
UOFW-1-15384		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US00/10920	21/04/2000	23/04/1999
International Patent Classification (IPC) or national classification and IPC		
C12N15/53		
Applicant		
UNIVERSITY OF WASHINGTON et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 16 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☒ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
13/11/2000	14.08.2001
Name and mailing address of the international preliminary examining authority:	Authorized officer
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Hix, R Telephone No. +31 70 340 3898

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/10920

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-66 as originally filed

Claims, No.:

1-65 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 11-43, 54-62.

because:

☒ the said international application, or the said claims Nos. 11-43, 54-62 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☒ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:
   see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☒ all parts.

   ☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2-5, 44-53, 64, 65
	No:	Claims	1, 6-10, 44, 63
Inventive step (IS)	Yes:	Claims	2-5
	No:	Claims	1, 6-10, 44-53, 63-65
Industrial applicability (IA)	Yes:	Claims	1-10, 44-53, 63-65
	No:	Claims	1, 7-9

2. Citations and explanations
   see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

   see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 11 to 43 encompass in vivo methods for treatment of the human or animal body by diagnostic methods and claims 54 to 62 involve in vivo methods for treatment of the human or animal body by therapeutic methods. The IPEA is not required to carry out an international preliminary examination on said subject-matter according to Article 34{4}{a}{I} and Rule 67.1{iv} PCT.

Re Item IV

Lack of unity of invention

The IPEA agrees with the ISA that the different subject-matters of the present application are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

Genes encoding polypeptides involved in androgen-regulation of the prostate are known in the prior art, see for example, the description page 2 and
DI: Nucleic Acids Research, 1997, vol. 25, no. 16, pages 3318-3325, Z. Sun et al.

In view of the state of the art the problem may therefore be defined as the provision of alternative genes and the corresponding polypeptides involved in the androgen regulation of the prostate.

The present application provides the solutions of polynucleotides and the encoded polypeptides which are predominantly expressed in the prostate gland; ARSDR1, TMPRSS2 and PART-1.

Consequently due to the fact that androgen-responsive polynucleotides are known in the state of the art, due to the fact that the different solutions are essentially different in terms of nucleotide and primary structure of the corresponding polypeptide and function and due to the absence of further technical features which could provide a common novel and inventive linking concept, the IPEA is of the opinion that there is no single inventive concept underlying the set of claimed inventions of the present application according to Rule 13.1 PCT.

There is therefore lack of unity and the different inventions, not belonging to a common inventive concept are formulated as the following different subjects according to Article 17{3}{a} PCT;

Invention 1: Claims 1, 7-16, 36, 54, 63-65 partially and claims 2-4, 17-19, 26-28. 37-41, 44-50, 55-57 completely: Isolated polynucleotides capable of hybridizing under stringent conditions to at least 15 contiguous nucleotides from SEQ ID NO: 1 and 8, substantially pure polypeptides consisting of SEQ ID NO: 2 encoding androgen-responsive polypeptide ARSDR1, methods of diagnosis or predicting susceptibility to a prostate neoplastic condition using ARSDR1, method of identifying compound that inhibits the activity of ARSDR1, methods of treatment involving administering ARSDR1 and antibodies raised against ARSDR1.

Invention 2: Claims 1, 7-9, 11-16, 36, 54, 63-65 partially and claims 5, 20-22, 29-31, 42-43, 51-53, 58-60 completely: Isolated polynucleotides capable of hybridizing under stringent conditions to at least 15 contiguous nucleotides from SEQ ID NO: 3, 9 and 10, substantially pure polypeptides consisting of SEQ ID NO: 4 encoding androgen-responsive polypeptide TMPRSS2, methods of diagnosis or predicting susceptibility to a prostate neoplastic condition using TMPRSS2, method of identifying compound that inhibits the activity of TMPRSS2, methods of treatment involving administering TMPRSS2 and antibodies raised against TMPRSS2.

Invention 3: Claims 1, 7-16, 36, 54, 63-65 partially and claims 6, 23-25, 32-35, 61-62 completely: Isolated polynucleotides capable of hybridizing under stringent conditions to at least 15 contiguous nucleotides from SEQ ID NO: 5 and 11, substantially pure polypeptides consisting of SEQ ID NO: 6 encoding androgen-responsive polypeptide PART-1, methods of diagnosis or predicting susceptibility to a prostate neoplastic condition using PART-1, method of identifying compound that inhibits the activity of PART-1, methods of treatment involving administering PART-1 and antibodies raised against PART-1.

Invention 4: Claims 1, 7-9, partially: Isolated polynucleotides capable of hybridizing under stringent conditions to at least 15 contiguous nucleotides from SEQ ID NO: 7 which encodes androgen-responsive polypeptide 8C3.

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Invention 1: Claims 1, 7-16, 36, 54, 63-65 partially and claims 2-4, 17-19, 26-28. 37-41, 44-50, 55-57 completely: Isolated polynucleotides capable of hybridizing under stringent conditions to at least 15 contiguous nucleotides from SEQ ID NO: 1 and 8, substantially pure polypeptides consisting of SEQ ID NO: 2 encoding androgen-responsive polypeptide ARSDR1, methods of diagnosis or predicting susceptibility to a prostate neoplastic condition using ARSDR1, method of identifying compound that inhibits the activity of ARSDR1, methods of treatment involving administering ARSDR1 and antibodies raised against ARSDR1.

CITATIONS
Reference is made to the following documents:

D1: WO-A-9 622 360 {Human Genome Sciences Inc.}
D2: EMBL Sequence data Accession number: AA442517
D3:EMBL Sequence data Accession number: AA035790
D4:EMBL Sequence data Accession number: AA454187

NOVELTY (Art. 33(2) PCT)

i. D1 discloses a human prostatic specific reductase with a 99.4% identity in 1087 nucleotides with SEQ ID NO: 1 and 97.7% in 308 amino acids with SEQ ID NO: 2. D1 also describes oligonucleotide probes, antibodies raised against the sequences and screening assays to identify agonists and antagonists.

ii. D2 discloses an EST with 99.6% identity with part of SEQ ID NO:1, D3 an EST with 100% identity with part of SEQ ID NO:1 and D4 an EST with 99.4% identity with part of SEQ ID NO:1.

iii. In the light of the above prior art, the present application does not satisfy the criterion set forth in Article 33(2) PCT because the

subject-matter of claims 1, 7 to 10, 44 and 63 is not new in respect of prior art as defined in the regulations (Rule 64(1)-(3) PCT).

INVENTIVE STEP (Art. 33(3) PCT)

iv. Document D1 is considered to represent the most relevant state of the art and discloses a human prostatic specific reductase having a high sequence homology to SEQ ID NO: 1 and 2 of the ARSDR1 of Invention 1 of the present application.

v. The subject-matter of claims 2 to 4 involving SEQ ID NO: 8 and fragments thereof is not disclosed in the prior art and is also not suggested by the prior art documents. The person skilled in the art would not consider it obvious that the nucleotide sequence SEQ ID NO: 8 encodes the 5' promoter and regulatory regions of the androgen-responsive polypeptide ARSDR1. The subject-matter of claims 2 to 4 is therefore considered to involve an inventive step according to Article 33{3} PCT.

vi. The subject-matter of claims 45 to 50 differs in the details of the method used to identify compounds that inhibit the activity of the ARSDR1. Said differences are simply alternatives which are obvious to the person skilled in the art for use in methods such as claim 44. Consequently the dependent claims 45 to 50 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, involve an inventive step according to Article 33{3} PCT.

Invention 2: Claims 1, 7-9, 11-16, 36, 54, 63-65 partially and claims 5, 20-22, 29-31, 42-43, 51-53, 58-60 completely: Isolated polynucleotides capable of hybridizing under stringent conditions to at least 15 contiguous nucleotides from SEQ ID NO: 3, 9 and 10, substantially pure polypeptides consisting of SEQ ID NO: 4 encoding androgen-responsive polypeptide TMPRSS2, methods of diagnosis or predicting susceptibility to a prostate neoplastic condition using TMPRSS2, method of identifying compound that inhibits the activity of TMPRSS2, methods of treatment involving administering TMPRSS2 and antibodies raised against TMPRSS2.

CITATIONS

Reference is made to the following documents:

D1: Genomics, 1997, vol. 44, pages 309-320, A. Paoloni-Giacobino et al.

D2: EMBL Database, Sequence Accession number AC005612, 9.9.98

NOVELTY (Art. 33(2) PCT)

I.} D1 discloses the cloning of TMPRSS2 gene, Accession no. U75329 which has a 99.308% identity in 2455 nucleotides with SEQ ID NO: 3 and a 100% identity in 492 amino acids with SEQ ID NO: 4. D2 involves the sequence with Accession number AC005612 which has a 100% identity in 2172 nucleotides with SEQ ID NO:10, and 99.468% in 2445 nucleotides with SEQ ID NO: 3.

ii.} The present application does not satisfy the criterion set forth in Article 33(2) PCT because the subject-matter of claim 1 is not new in respect of prior art as defined in the regulations (Rule 64(1)-(3) PCT).

INVENTIVE STEP (Art. 33(3) PCT)

iv.} Document D1 is considered to represent the most relevant state of the art and discloses the isolation of full-length TMPRSS2 coding sequences. The subject-matter of claims 7, 51 and 63 differs in that they involve fragments of said TMPRSS2 sequence for use as probes, a method of identifying a compound that inhibits the activity of TMPRSS2 and antibodies that specifically bind to TMPRSS2.

v.} Due to the fact that the entire coding sequence of TMPRSS2 is disclosed in the prior art D1, the person skilled in the art would consider the isolation of probes comprising at least 15 contiguous nucleotides from the known SEQ ID NO: 3 of the present application simply a matter of routine procedure. Similarly a method for the identification of compounds that inhibit the activity of TMPRSS2 and antibodies raised against TMPRSS2 are both routine procedures once the whole sequence encoding TMPRSS2 is fully known and characterized.

vi.} Consequently the subject-matter of claims 7 to 9, 51 to 53 and 63 to 65 is considered not to involve an inventive step according to Article 33{3} PCT.

Invention 3: Claims 1, 7-16, 36, 54, 63-65 partially and claims 6, 23-25, 32-35, 61-62 completely: Isolated polynucleotides capable of hybridizing under stringent conditions to at least 15 contiguous nucleotides from SEQ ID NO: 5 and 11, substantially pure polypeptides consisting of SEQ ID NO: 6 encoding androgen-responsive polypeptide PART-1, methods of diagnosis or predicting susceptibility to a prostate neoplastic condition using PART-1, method of identifying compound that inhibits the activity of PART-1, methods of treatment involving administering PART-1 and antibodies raised against PART-1.

CITATIONS

Reference is made to the following documents:

D1: Proc. Natl. Acad. Sci. USA, July 1993, vol. 90, pp. 6061-6065, M.A. van Dijk et al.

D2: Cancer Research, vol. 60, 15th February 2000, pages 858-863, B. Lin et al.

NOVELTY (Art. 33(2) PCT) & INVENTIVE STEP (Art. 33(3) PCT)

I.} D1 discloses an investigation of the DNA-binding properties of the Pbx1 homeodomain. The Pbx1 homeodomain preferentially binds to DNA at sites containing the nucleotide sequence ATCAATCAA.

ii.} Although D2 is published after the priority date of the present application, the disclosures of D2 are used to interpret the teachings of D1. D2 discloses the PART-1

cDNA and analysis of the putative PART-1 promoter region identified a potential binding site for the homeobox gene PBX-1a, but no consensus androgen response element or sterol-regulatory element binding sites were identified.

iii.} The teachings of D1 therefore anticipate the subject-matter of the present claims 1 and 6 which are not novel according to Article 33{2} PCT.

iv.} As the PART-1 cDNA and putative protein are not significantly homologous to any sequences in the public databases. The closest prior art is considered to be represented by D1 as the Pbx-1 protein contains a homeobox domain where a putative binding site is present in the promoter region of PART-1.

v.} The person skilled in the art aware of the disclosures of the available prior art documents would neither anticipate nor expect the identification of a novel human prostate-specific, androgen-regulated gene as provided by PART-1.

vi.} In the light of the prior art available, the subject-matter of Claims 7-10 and 63-65 partially, as far as they relate to the subject-matter of Invention 3, is neither disclosed nor suggested in the prior art and therefore appears to satisfy the criteria of novelty and inventive step as required by Articles 33{2} and {3} PCT.

Invention 4: Claims 1, 7-9, partially: Isolated polynucleotides capable of hybridizing under stringent conditions to at least 15 contiguous nucleotides from SEQ ID NO: 7 which encodes androgen-responsive polypeptide 8C3.

CITATIONS

Reference is made to the following documents:

D1: WO-A-9 903 990 (HUMAN GENOME SCIENCES INC)

a. NOVELTY (Art. 33(2) PCT)

i. The closest prior art to the subject-matter of Invention 4 and SEQ ID NO: 7 is represented by D1 which discloses a nucleic acid sequence with 99.6% identity in 900 nucleic acid overlap with the 5217 nucleic acid length of SEQ ID NO:7 of the present application.

ii. The subject-matter of claims 1 and 7 to 9 as far as they relate to the Invention 4 is considered to satisfy the criterion set forth in Article 33(2) PCT because the subject-matter of said claims is new in respect of prior art as defined in the regulations (Rule 64(1)-(3) PCT).

b. INVENTIVE STEP & INDUSTRIAL APPLICABILITY (Art. 33(3)(4) PCT)

i. Document D1 is considered to represent the most relevant state of the art as it discloses a nucleic acid with the closest identity to SEQ ID NO: 7 of Invention 4.

ii. According to the description page 22, paragraph 1, 8C3 is an androgen-regulated transcript where the cDNA has been mapped to 16Q24 and it is speculated that 8C3 is likely to be a tumor suppressor.

iii. However, without a specific function 8C3 cannot be considered to solve any technical problem and therefore cannot be considered to involve an inventive step or have any industrial applicability. The subject-matter of claims 1 and 7 to 9 as far as they relate to Invention 4 are therefore considered to contravene the requirements of Articles 33{3} and {4} PCT.

Re Item VI

Certain documents cited

WO-A-0 004 149 {Corixa Corp.} published on 27.1.2000, filed on 14.7.99 and claiming priority from 14.7.98, 23.9.98, 15.1.99 and 9.4.99.
WO-A-0 029 448 {Sagami Chemical Research Center} published on 25.5.2000, filed on 17.11.99 and claiming priority from 17.11.98, 22.12.98, 16.3.99, 27.4.99 and 19.5.99.

* Although WO-A-0 004 149 {Corixa Corp.} and WO-A-0 029 448 {Sagami Chemical Research Center} do not constitute prior art within the meaning of Rule 64.1(b), they appear to disclose sequences with high homology to SEQ ID NO: 1 and 2 of Invention

1. They might therefore be taken into consideration in the regional phase before the EPO. No check has been made as to whether the priority of this application has been validly claimed.

WO-A-0 000 605 {Myriad Genetics Inc.} published on 6.1.2000, filed on 29.6.99 and claiming priority from 29.6.98.
WO-A-0 012 758 {Diadexus LLC.} published on 9.3.2000 , filed on 1.9.99 and claiming priority from 2.9.98.
WO-A-0 018 961 {Millenium Pharmaceuticals Inc.} published on 6.4.2000 , filed on 30.9.1999 and claiming priority from 30.9.98.
WO-A-0 023 111 {Dladexus LLC.} published on 27.4.2000, filed on 19.10.99 and claiming priority from 19.10.98.

* Although WO-A-0 000 605 {Myriad Genetics Inc.}, WO-A-0 012 758 {Diadexus LLC.}, WO-A-0 018 961 {Millenium Pharmaceuticals Inc.} and WO-A-0 023 111 {Dladexus LLC.} do not constitute prior art within the meaning of Rule 64.1(b), they all appear to disclose sequences with high homology with SEQ ID NOS, 3, 4 and 10 of the present application and claims 1,5,7-9,11-16,20-22,29-31,36,42,43,51-54,58-60 and 63-65 as far as the subject-matter of Invention 2 is concerned. They might therefore be taken into consideration in the regional phase before the EPO. No check has been made as to whether the priority of this application has been validly claimed.

WO-A-9 962 942 {Urogenesys, Inc.} published on 9.12.99 , filed on 1.6.99 and claiming priority from 1.6.98, 29.6.98 and 14.4.99.

* Although WO-A-9 962, 942 does not constitute prior art within the meaning of Rule 64.1(b), it appears to disclose nucleic acid sequences with 99.520% identity in 1668 nucleotides with SEQ ID NO: 3 of the present application and so the features of claims 1,5,7-9,11-16,20-22,29-31,36,42,43,51-54,58-60,63-65, as far as they involve the subject-matter of Invention 2. It might therefore be taken into consideration in the regional phase before the EPO. No check has been made as to whether the priority of this application has been validly claimed.

The priority documents pertaining to the present application were not available at the time of establishing this first written opinion. Hence, it is based on the assumption that

all claims enjoy priority rights from the filing date of the priority document. If it later turns out that this is not correct, the above document (cf page) cited in the international search report could become relevant to assess whether the claimed subject matter satisfy the criteria set forth in Art. 33(1) PCT.

Re Item VII

Certain defects in the international application

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the above cited documents is not mentioned in the description, nor are these documents identified therein.

2. If amendments are filed, it should be by way of replacement pages in the manner stipulated by Rule 66.8(a) PCT. In particular, fair copies of the amendments should be filed preferably in triplicate. Moreover, the applicant's attention is drawn to the fact that, as a consequence of Rule 66.8(a) PCT the examiner is not permitted to carry out any amendments under the PCT procedure, however minor these may be.

3. In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT). If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

4. The applicant is requested to note that in accordance with Rule 66.4 (a) PCT the issuance of an additional Written Opinion (WO) is facultative. Moreover, as the final action in the PCT procedure is an International Preliminary Examination Report (IPER) and not a decision, a violation of the right to be heard cannot exist. The applicant can not therefore rely on obtaining a second WO before the IPER is issued and is requested to answer this first WO in a complete manner.

Re Item VIII

Certain observations on the international application

1 The application does not meet the requirements of Article 6 PCT because claims are not clear for the following reasons:

1.1 Claims 1 and 7 include the term "at least 15 contiguous nucleotides" where the sequence is "selected from the group consisting of SEQ ID ....". Said phrase is vague and open to interpretation as it is not clear which sequences are actually encompassed within the scope of the claims and as such the scope of claims 1 and 7 is rendered unclear according to Article 6 PCT.

1.2 The terms "substantially" in claim 2 and "functional fragments thereof" are unclear particularly in the absence of a defined function.

2 The vague and imprecise statement in the description on page 66 implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them (see also the PCT Guidelines, PCT/GL/3 III, 4.3a).

3 The description page 8, lines 24 to 35 specifies particular ESTs that the applicant states are "specifically excluded as fragments of the invention", however for this actually to be the case the Applicant must insert a specific disclaimer to these ESTs into the relevant claims.

To: PLR

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

To:
Christensen O'Connor Johnson & Kindness PLLC
Attn. BRADLEY,Douglas R.
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
UNITED STATES OF AMERICA

RECEIVED
DOCKETING
FEB 12 2001
CHRISTENSEN, O'CONNOR JOHNSON & KINDNESS PLLC

Date of mailing *(day/month/year)*	07/02/2001
Applicant's or agent's file reference: UOFW-1-15384	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No.: PCT/US 00/10920	International filing date *(day/month/year)*: 21/04/2000
Applicant: UNIVERSITY OF WASHINGTON et al.	

1. [X] The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Fascimile No.: (41-22) 740.14.35

DOCKETED

For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

[ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

[ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Catherine Humbert

Form PCT/ISA/220 (July 1998)

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the International application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped),whether

(i) the claim is unchanged;

(ii) the claim is cancelled;

(iii) the claim is new;

(iv) the claim replaces one or more claims as filed;

(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
UOFW-1-15384		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 00/10920	21/04/2000	23/04/1999
Applicant		
UNIVERSITY OF WASHINGTON et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 11 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [X] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [X] furnished subsequently to this Authority in computer readble form.

   [X] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [X] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [X] **Certain claims were found unsearchable** (See Box I).

3. [X] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. --

   [ ] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 00/10920

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1, 7-16, 36, 54, 63-65 partially and claims 2-4, 17-19, 26-28. 37-41, 44-50, 55-57 completely

Isolated polynucleotides capable of hybridizing under stringent conditions to at least 15 contiguous nucleotides from SEQ ID NO: 1 and 8, substantially pure polypeptides consisting of SEQ ID NO: 2 encoding androgen-responsive polypeptide ARSDR1, methods of diagnosis or predicting susceptibility to a prostate neoplastic condition using ARSDR1, method of identifying compound that inhibits the activity of ARSDR1, methods of treatment involving administering ARSDR1 and antibodies raised against ARSDR1.

2. Claims: 1, 7-9, 11-16, 36, 54, 63-65 partially and claims 5, 20-22, 29-31, 42-43, 51-53, 58-60 completely

Isolated polynucleotides capable of hybridizing under stringent conditions to at least 15 contiguous nucleotides from SEQ ID NO: 3, 9 and 10, substantially pure polypeptides consisting of SEQ ID NO: 4 encoding androgen-responsive polypeptide TMPRSS2, methods of diagnosis or predicting susceptibility to a prostate neoplastic condition using TMPRSS2, method of identifying compound that inhibits the activity of TMPRSS2, methods of treatment involving administering TMPRSS2 and antibodies raised against TMPRSS2.

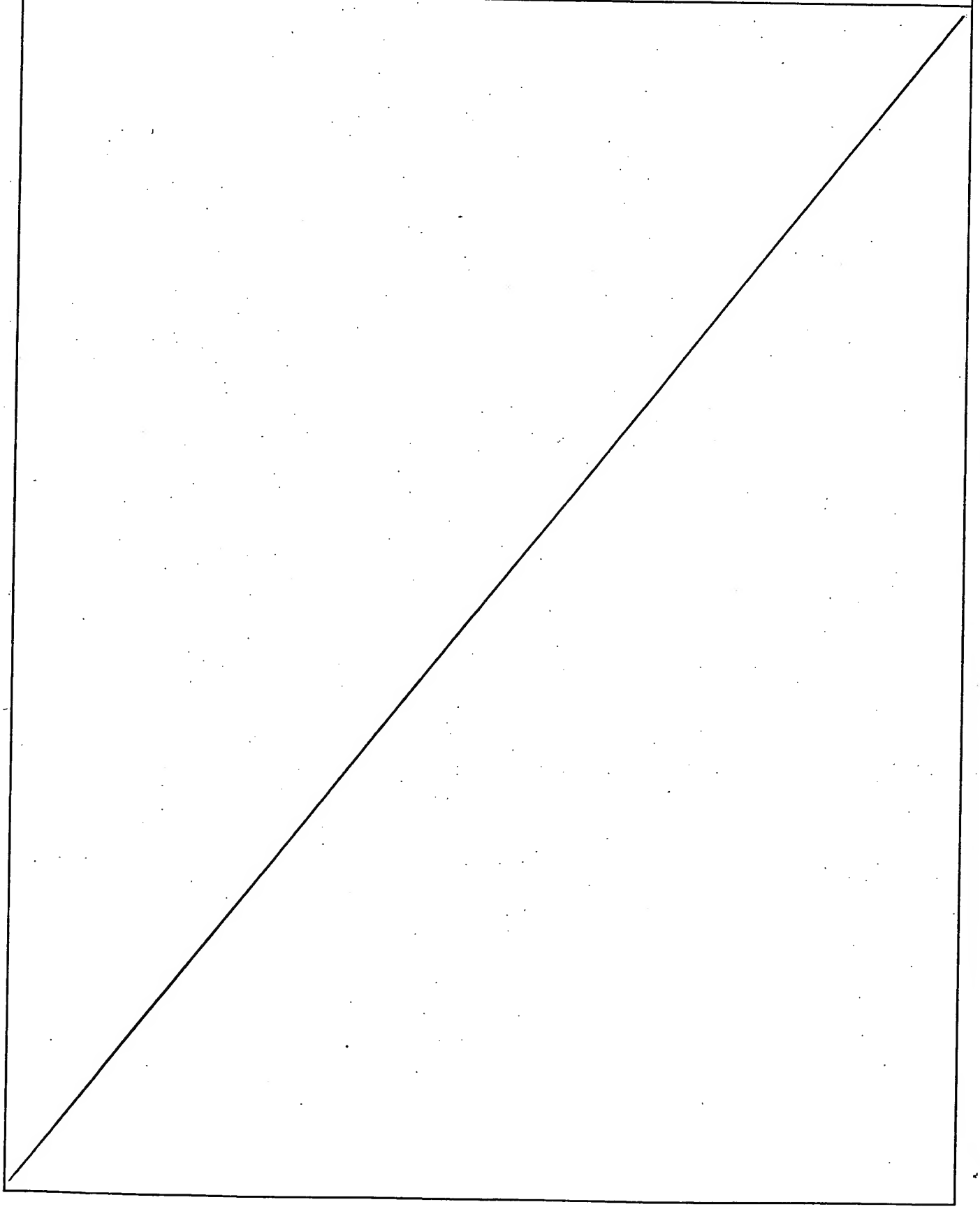
3. Claims: 1, 7-16, 36, 54, 63-65 partially and claims 6, 23-25, 32-35, 61-62 completely

Isolated polynucleotides capable of hybridizing under stringent conditions to at least 15 contiguous nucleotides from SEQ ID NO: 5 and 11, substantially pure polypeptides consisting of SEQ ID NO: 6 encoding androgen-responsive polypeptide PART-1, methods of diagnosis or predicting susceptibility to a prostate neoplastic condition using PART-1, method of identifying compound that inhibits the activity of PART-1, methods of treatment involving administering PART-1 and antibodies raised against PART-1.

4. Claims: 1, 7-9, partially

Isolated polynucleotides capable of hybridizing under stringent conditions to at least 15 contiguous nucleotides from SEQ ID NO: 7 which encodes androgen-responsive polypeptide 8C3.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210



FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Although claim(s) 11 to 43 are directed to a diagnostic method practised on the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Although claims 54 to 62 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/10920

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C12N15/53 C12N15/57 C12N9/02 C12N9/64 C12Q1/32
C12Q1/37 C07K16/40 A61K38/44 A61K38/48 A61K48/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C12N C12Q C07K A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
STRAND, BIOSIS, WPI Data, CAB Data, EPO-Internal, PAJ, EMBASE, MEDLINE, EMBL

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 22360 A (HUMAN GENOME SCIENCES INC ;HE WEI WU (US); MEISSNER PAUL S (US); H) 25 July 1996 (1996-07-25) the whole document ---	1-4, 7-19, 26-28, 36-41, 44-50, 54-57, 63-65
X	DATABASE EBI [Online] 4 June 1997 (1997-06-04) L. HILLIER ET AL.: "Accession no. AA442517" XP002147799 cited in the application abstract --- -/--	1,7

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 January 2001	07. 02. 2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Hix, R

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE EBI [Online] 26 August 1996 (1996-08-26) L. HILLIER ET AL.: "Accession number AA035790" XP002147800 cited in the application abstract ---	1,7
X	DATABASE EBI [Online] 11 July 1997 (1997-07-11) L. HILLIER ET AL.: "Accession number AA454187" XP002147801 cited in the application abstract ---	1,7
P,X	WO 99 62942 A (SAFFRAN DOUGLAS C ;AFAR DANIEL E (US); HUBERT RENE S (US); LEONG K) 9 December 1999 (1999-12-09) the whole document ---	1,5,7-9, 11-16, 20-22, 29-31, 36,42, 43, 51-54, 58-60, 63-65
P,X	WO 00 04149 A (CORIXA CORP) 27 January 2000 (2000-01-27) the whole document ---	1-4, 7-19, 26-28, 36-41, 44-50, 54-57, 63-65
P,X	DE 198 13 839 A (METAGEN GES FUER GENOMFORSCHUN) 23 September 1999 (1999-09-23) the whole document ---	1-4, 7-19, 26-28, 36-41, 44-50, 54-57, 63-65
E	WO 00 29448 A (KATO SEISHI ;KIMURA TOMOKO (JP); PROTEGENE INC (JP); SAGAMI CHEM R) 25 May 2000 (2000-05-25) the whole document --- -/--	1-4, 7-19, 26-28, 36-41, 44-50, 54-57, 63-65

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	C-H. LAI ET AL.: "Identification of novel human genes evolutionarily conserved in Caenorhabditis elegans by comparative proteomics." GENOME RESEARCH, vol. 10, no. 5, 2000, pages 703-713, XP000929862 the whole document	1-4, 7-19, 26-28, 36-41, 44-50, 54-57, 63-65
A	P.J. ROCHE ET AL.: "A consensus DNA-binding site for the androgen-receptor." MOLECULAR ENDOCRINOLOGY, vol. 6, no. 12, December 1992 (1992-12), pages 2229-2235, XP000934123 cited in the application the whole document	
A	V. HAWKINS ET AL.: "PEDB: the Prostate expression database." NUCLEIC ACIDS RESEARCH, vol. 27, no. 1, 1999, pages 204-208, XP000933960 cited in the application the whole document	
A	Z- SUN ET AL.: "Androgen receptor-associated protein complex binds upstream of the androgen-responsive elements in the promoters of human prostate-specific antigen and kallikrein 2 gene." NUCLEIC ACIDS RESEARCH, vol. 25, no. 16, 1997, pages 3318-3325, XP002147416 the whole document	
A	WO 99 03990 A (FLORENCE KIMBERLY A ;HUMAN GENOME SCIENCES INC (US); FENG PING (US) 28 January 1999 (1999-01-28) sequence Accession number X22248, claim 4, page 189 the whole document	1,7-9
P,A	WO 99 33982 A (CHIRON CORP ;HYSEQ INC (US)) 8 July 1999 (1999-07-08) the whole document	1,7-9

-/--

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	LIN B ET AL: "PART-1: A NOVEL HUMAN PROSTATE-SPECIFIC, ANDROGEN-REGULATED GENE THAT MAPS TO CHROMOSOME 5Q12" CANCER RESEARCH,AMERICAN ASSOCIATION FOR CANCER RESEARCH, BALTIMORE, MD,US, vol. 60, no. 4, 15 February 2000 (2000-02-15), pages 858-863, XP000929855 ISSN: 0008-5472 the whole document	1,6-16, 23-25, 32-36, 54,61-65
A	M.A. VAN DIJK ET AL.: "Pbx1 is converted into a trascriptional activator upon acquiring the N-terminal region of E2A in pre-B-cell acute lymphoblastoid leukemia." PROC. NATL. ACAD. SCI. USA, vol. 90, July 1993 (1993-07), pages 6061-6065, XP000978872 cited in the application the whole document	1,6-16, 23-25, 32-36, 54,61-65
A	DATABASE EMBL [Online] Accession number AA410580, 5 May 1997 (1997-05-05) L. HILLIER ET AL.: "WashU-Merck EST Project 1997" XP002158122 cited in the application Sequence data abstract	1,6-16, 23-25, 32-36, 54,61-65
X	PAOLONI-GIACOBINO A ET AL: "CLONING OF THE TMPRSS2 GENE, WHICH ENCODES A NOVEL SERINE PROTEASE WITH TRANSMEMBRANE, LDLRA, AND SRCR DOMAINS AND MAPS TO 21Q22.3" GENOMICS,US,ACADEMIC PRESS, SAN DIEGO, vol. 44, no. 3, 15 September 1997 (1997-09-15), pages 309-320, XP000856785 ISSN: 0888-7543 Sequence Accession no. U75329	1,5,7-9, 11-16, 20-22, 29-31, 36,42, 43, 51-54, 58-60, 63-65
X	DATABASE EMBL [Online] Accession number: AC005612, 9 September 1998 (1998-09-09) W. KIMMERLY ET AL.: "Sequencing of human chromosome 21." XP002158123 sequence data abstract	1,5,7-9, 11-16, 20-22, 29-31, 36,42, 43, 51-54, 58-60, 63-65

-/--

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DATABASE EMBL [Online] accession number AI393270, 5 February 1999 (1999-02-05) NATIONAL CANER INSTITUTE: "Homo sapiens cDNA clone" XP002158124 cited in the application sequence data abstract	1,5,7-9, 11-16, 20-22, 29-31, 36,42, 43, 51-54, 58-60, 63-65
P,X	LIN B ET AL: "PROSTATE-LOCALIZED AND ANDROGEN-REGULATED EXPRESSION OF THE MEMBRANE-BOUND SERINE PROTEASE TMPRSS2" CANCER RESEARCH,AMERICAN ASSOCIATION FOR CANCER RESEARCH, BALTIMORE, MD,US, vol. 59, 1 September 1999 (1999-09-01), pages 4180-4184, XP000929801 ISSN: 0008-5472 the whole document	1,5,7-9, 11-16, 20-22, 29-31, 36,42, 43, 51-54, 58-60, 63-65
P,X	WO 00 00605 A (MYRIAD GENETICS INC) 6 January 2000 (2000-01-06) the whole document	1,5,7-9, 11-16, 20-22, 29-31, 36,42, 43, 51-54, 58-60, 63-65
P,X	WO 00 12758 A (RECIPON HERVE ;DIADEXUS LLC (US); SALCEDA SUSANA (US); SUN YONGMIN) 9 March 2000 (2000-03-09) sequences Z90478 and Y57280 page 49 -page 50; claim 9	1,5,7-9, 11-16, 20-22, 29-31, 36,42, 43, 51-54, 58-60, 63-65

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 00 18961 A (MACBETH KYLE J ;SHYJAN ANDREW W (US); MILLENNIUM PHARM INC (US)) 6 April 2000 (2000-04-06) Sequence A08803 page 108; claim 1; figure 3 ---	1,5,7-9, 11-16, 20-22, 29-31, 36,42, 43, 51-54, 58-60, 63-65
E	WO 00 23111 A (RECIPON HERVE ;DIADEXUS LLC (US); SALCEDA SUSANA (US); CAFFERKEY R) 27 April 2000 (2000-04-27) Sequence Z95005 page 57 -page 58; claim 7 -----	1,5,7-9, 11-16, 20-22, 29-31, 36,42, 43, 51-54, 58-60, 63-65

INTERNATIONAL SEARCH REPORT

...on on patent family members

International Application No
...US 00/10920

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		EP 0804546 A	05-11-1997
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DE 19813839 A	23-09-1999	WO 9947669 A	23-09-1999
		EP 1064379 A	03-01-2001
WO 0029448 A	25-05-2000	AU 1181900 A	05-06-2000
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		AU 6164099 A	17-04-2000
		WO 0018782 A	06-04-2000
WO 0023111 A	27-04-2000	NONE	

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
2 November 2000 (02.11.2000)

PCT

(10) International Publication Number
WO 00/65067 A3

(51) International Patent Classification[7]: C12N 15/53, 15/57, 9/02, 9/64, C12Q 1/32, 1/37, C07K 16/40, A61K 38/44, 38/48, 48/00

(21) International Application Number: PCT/US00/10920

(22) International Filing Date: 21 April 2000 (21.04.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/130,778	23 April 1999 (23.04.1999)	US
60/151,585	30 August 1999 (30.08.1999)	US
60/174,003	30 December 1999 (30.12.1999)	US
60/177,751	24 January 2000 (24.01.2000)	US

(71) Applicant *(for all designated States except US)*: **UNIVERSITY OF WASHINGTON** [US/US]; Office of Technology Transfer, 1107 N.E. 45th Street, Suite 200, Seattle, WA 98105-4631 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **NELSON, Peter, S.** [US/US]; 5121 27th Avenue N.E., Seattle, WA 98105 (US). **HOOD, Leroy** [US/US]; 6411 N.E. Windermer Drive, Seattle, WA 98105 (US). **LIN, Biaoyang** [CN/US]; 13716 15th Avenue N.E., #204, Seattle, WA 98125 (US).

(74) Agent: **BRADLEY, R., Douglas**; Christensen O'Connor Johnson & Kindness PLLC, Suite 2800, 1420 Fifth Avenue, Seattle, WA 98101 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(88) Date of publication of the international search report:
2 August 2001

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PROSTATE-SPECIFIC POLYNUCLEOTIDES, POLYPEPTIDES AND THEIR METHODS OF USE

(57) Abstract: The invention provides isolated polynucleotides encoding prostate-specific, androgen-regulated polypeptides. The invention also provides substantially pure polynucleotides corresponding to genomic regulator regions of prostate-specific, androgen-regulated polynucleotides. Fragments and probes of polynucleotides thereof are also provided. The invention further provides a method of diagnosing or predicting the susceptibility of a prostate neoplastic condition in an individual suspected of having a neoplastic condition of the prostate. The method consists of: (a) obtaining a fluid or prostate sample of the individual; (b) determining the expression level of the prostate-specific, androgen-regulated polynucleotide or polypeptide, and (c) comparing the expression levels of the prostate-specific, androgen-regulated polynucleotide or polypeptide to expression levels from a normal fluid sample, from normal prostate cells or from an androgen-dependent cell line, wherein a two-fold change in expression level of the prostate-specific, androgen-regulated polynucleotide or polypeptide in the individual fluid or prostate sample as compared to the normal fluid or normal prostate cells or an androgen-dependent cell line indicates the presence of a prostate neoplastic condition. Methods of identifying compounds that selectively inhibit or increase prostate-specific polypeptides of the invention and a method of treating or reducing the progression of a prostate neoplastic condition are also provided.

WO 00/65067 A3

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/10920

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C12N15/53 C12N15/57 C12N9/02 C12N9/64 C12Q1/32
C12Q1/37 C07K16/40 A61K38/44 A61K38/48 A61K48/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C12N C12Q C07K A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
STRAND, BIOSIS, WPI Data, CAB Data, EPO-Internal, PAJ, EMBASE, MEDLINE, EMBL

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 22360 A (HUMAN GENOME SCIENCES INC ;HE WEI WU (US); MEISSNER PAUL S (US); H) 25 July 1996 (1996-07-25) the whole document	1-4, 7-19, 26-28, 36-41, 44-50, 54-57, 63-65
X	DATABASE EBI 'Online! 4 June 1997 (1997-06-04) L. HILLIER ET AL.: "Accession no. AA442517" XP002147799 cited in the application abstract	1,7

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search	Date of mailing of the international search report
22 January 2001	07 02 2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Hix, R

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE EBI 'Online! 26 August 1996 (1996-08-26) L. HILLIER ET AL.: "Accession number AA035790" XP002147800 cited in the application abstract	1,7
X	DATABASE EBI 'Online! 11 July 1997 (1997-07-11) L. HILLIER ET AL.: "Accession number AA454187" XP002147801 cited in the application abstract	1,7
P,X	WO 99 62942 A (SAFFRAN DOUGLAS C ;AFAR DANIEL E (US); HUBERT RENE S (US); LEONG K) 9 December 1999 (1999-12-09) the whole document	1,5,7-9, 11-16, 20-22, 29-31, 36,42, 43, 51-54, 58-60, 63-65
P,X	WO 00 04149 A (CORIXA CORP) 27 January 2000 (2000-01-27) the whole document	1-4, 7-19, 26-28, 36-41, 44-50, 54-57, 63-65
P,X	DE 198 13 839 A (METAGEN GES FUER GENOMFORSCHUN) 23 September 1999 (1999-09-23) the whole document	1-4, 7-19, 26-28, 36-41, 44-50, 54-57, 63-65
E	WO 00 29448 A (KATO SEISHI ;KIMURA TOMOKO (JP); PROTEGENE INC (JP); SAGAMI CHEM R) 25 May 2000 (2000-05-25) the whole document	1-4, 7-19, 26-28, 36-41, 44-50, 54-57, 63-65

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
P,X	C-H. LAI ET AL.: "Identification of novel human genes evolutionarily conserved in Caenorhabditis elegans by comparative proteomics." GENOME RESEARCH, vol. 10, no. 5, 2000, pages 703-713, XP000929862 the whole document	1-4, 7-19, 26-28, 36-41, 44-50, 54-57, 63-65
A	P.J. ROCHE ET AL.: "A consensus DNA-binding site for the androgen-receptor." MOLECULAR ENDOCRINOLOGY, vol. 6, no. 12, December 1992 (1992-12), pages 2229-2235, XP000934123 cited in the application the whole document	
A	V. HAWKINS ET AL.: "PEDB: the Prostate expression database." NUCLEIC ACIDS RESEARCH, vol. 27, no. 1, 1999, pages 204-208, XP000933960 cited in the application the whole document	
A	Z- SUN ET AL.: "Androgen receptor-associated protein complex binds upstream of the androgen-responsive elements in the promoters of human prostate-specific antigen and kallikrein 2 gene." NUCLEIC ACIDS RESEARCH, vol. 25, no. 16, 1997, pages 3318-3325, XP002147416 the whole document	
A	WO 99 03990 A (FLORENCE KIMBERLY A ;HUMAN GENOME SCIENCES INC (US); FENG PING (US) 28 January 1999 (1999-01-28) sequence Accession number X22248, claim 4, page 189 the whole document	1,7-9
P,A	WO 99 33982 A (CHIRON CORP ;HYSEQ INC (US)) 8 July 1999 (1999-07-08) the whole document	1,7-9

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
P,X	LIN B ET AL: "PART-1: A NOVEL HUMAN PROSTATE-SPECIFIC, ANDROGEN-REGULATED GENE THAT MAPS TO CHROMOSOME 5Q12" CANCER RESEARCH,AMERICAN ASSOCIATION FOR CANCER RESEARCH, BALTIMORE, MD,US, vol. 60, no. 4, 15 February 2000 (2000-02-15), pages 858-863, XP000929855 ISSN: 0008-5472 the whole document	1,6-16, 23-25, 32-36, 54,61-65
A	M.A. VAN DIJK ET AL.: "Pbx1 is converted into a trascriptional activator upon acquiring the N-terminal region of E2A in pre-B-cell acute lymphoblastoid leukemia." PROC. NATL. ACAD. SCI. USA, vol. 90, July 1993 (1993-07), pages 6061-6065, XP000978872 cited in the application the whole document	1,6-16, 23-25, 32-36, 54,61-65
A	DATABASE EMBL 'Online! Accession number AA410580, 5 May 1997 (1997-05-05) L. HILLIER ET AL.: "WashU-Merck EST Project 1997" XP002158122 cited in the application Sequence data abstract	1,6-16, 23-25, 32-36, 54,61-65
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X	DATABASE EMBL 'Online! Accession number: AC005612, 9 September 1998 (1998-09-09) W. KIMMERLY ET AL.: "Sequencing of human chromosome 21." XP002158123 sequence data abstract	1,5,7-9, 11-16, 20-22, 29-31, 36,42, 43, 51-54, 58-60, 63-65

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	DATABASE EMBL 'Online! accession number AI393270, 5 February 1999 (1999-02-05) NATIONAL CANER INSTITUTE: "Homo sapiens cDNA clone" XP002158124 cited in the application sequence data abstract	1,5,7-9, 11-16, 20-22, 29-31, 36,42, 43, 51-54, 58-60, 63-65
P,X	LIN B ET AL: "PROSTATE-LOCALIZED AND ANDROGEN-REGULATED EXPRESSION OF THE MEMBRANE-BOUND SERINE PROTEASE TMPRSS2" CANCER RESEARCH,AMERICAN ASSOCIATION FOR CANCER RESEARCH, BALTIMORE, MD,US, vol. 59, 1 September 1999 (1999-09-01), pages 4180-4184, XP000929801 ISSN: 0008-5472 the whole document	1,5,7-9, 11-16, 20-22, 29-31, 36,42, 43, 51-54, 58-60, 63-65
P,X	WO 00 00605 A (MYRIAD GENETICS INC) 6 January 2000 (2000-01-06) the whole document	1,5,7-9, 11-16, 20-22, 29-31, 36,42, 43, 51-54, 58-60, 63-65
P,X	WO 00 12758 A (RECIPON HERVE ;DIADEXUS LLC (US); SALCEDA SUSANA (US); SUN YONGMIN) 9 March 2000 (2000-03-09) sequences Z90478 and Y57280 page 49 -page 50; claim 9	1,5,7-9, 11-16, 20-22, 29-31, 36,42, 43, 51-54, 58-60, 63-65

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 00 18961 A (MACBETH KYLE J ;SHYJAN ANDREW W (US); MILLENNIUM PHARM INC (US)) 6 April 2000 (2000-04-06) Sequence A08803 page 108; claim 1; figure 3	1,5,7-9, 11-16, 20-22, 29-31, 36,42, 43, 51-54, 58-60, 63-65
E	WO 00 23111 A (RECIPON HERVE ;DIADEXUS LLC (US); SALCEDA SUSANA (US); CAFFERKEY R) 27 April 2000 (2000-04-27) Sequence Z95005 page 57 -page 58; claim 7	1,5,7-9, 11-16, 20-22, 29-31, 36,42, 43, 51-54, 58-60, 63-65

INTERNATIONAL SEARCH REPORT

ational application No.
PCT/US 00/10920

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1, 7-16, 36, 54, 63-65 partially and claims 2-4, 17-19, 26-28. 37-41, 44-50, 55-57 completely

Isolated polynucleotides capable of hybridizing under stringent conditions to at least 15 contiguous nucleotides from SEQ ID NO: 1 and 8, substantially pure polypeptides consisting of SEQ ID NO: 2 encoding androgen-responsive polypeptide ARSDR1, methods of diagnosis or predicting susceptibility to a prostate neoplastic condition using ARSDR1, method of identifying compound that inhibits the activity of ARSDR1, methods of treatment involving administering ARSDR1 and antibodies raised against ARSDR1.

2. Claims: 1, 7-9, 11-16, 36, 54, 63-65 partially and claims 5, 20-22, 29-31, 42-43, 51-53, 58-60 completely

Isolated polynucleotides capable of hybridizing under stringent conditions to at least 15 contiguous nucleotides from SEQ ID NO: 3, 9 and 10, substantially pure polypeptides consisting of SEQ ID NO: 4 encoding androgen-responsive polypeptide TMPRSS2, methods of diagnosis or predicting susceptibility to a prostate neoplastic condition using TMPRSS2, method of identifying compound that inhibits the activity of TMPRSS2, methods of treatment involving administering TMPRSS2 and antibodies raised against TMPRSS2.

3. Claims: 1, 7-16, 36, 54, 63-65 partially and claims 6, 23-25, 32-35, 61-62 completely

Isolated polynucleotides capable of hybridizing under stringent conditions to at least 15 contiguous nucleotides from SEQ ID NO: 5 and 11, substantially pure polypeptides consisting of SEQ ID NO: 6 encoding androgen-responsive polypeptide PART-1, methods of diagnosis or predicting susceptibility to a prostate neoplastic condition using PART-1, method of identifying compound that inhibits the activity of PART-1, methods of treatment involving administering PART-1 and antibodies raised against PART-1.

4. Claims: 1, 7-9, partially

Isolated polynucleotides capable of hybridizing under stringent conditions to at least 15 contiguous nucleotides from SEQ ID NO: 7 which encodes androgen-responsive polypeptide 8C3.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Although claim(s) 11 to 43 are directed to a diagnostic method practised on the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Although claims 54 to 62 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

INTERNATIONAL SEARCH REPORT

..information on patent family members

Inte[redacted]nal Application No
PCT/US 00/10920

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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WO 0023111 A	27-04-2000	NONE	

PATENT COOPERATION TREATY

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NOTIFICATION OF ELECTION

(PCT Rule 61.2)

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Date of mailing (day/month/year) 04 December 2000 (04.12.00)	
International application No. PCT/US00/10920	**Applicant's or agent's file reference** UOFW-1-15384
International filing date (day/month/year) 21 April 2000 (21.04.00)	**Priority date** (day/month/year) 23 April 1999 (23.04.99)
Applicant NELSON, Peter, S. et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

13 November 2000 (13.11.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

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